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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,464	08/13/2001	William J. Boyle	ACS-57080	6454
24201	7590	11/16/2005	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/928,464	<b>Applicant(s)</b> BOYLE ET AL.	
	<b>Examiner</b> Melissa A. McCorkle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7, 8, 29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 29, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Curelaru et al (4,581,019). Curelaru et al discloses a delivery sheath (fig 2) comprising an elongate tube having a proximal end (1) and a distal end (2), and a resealable longitudinal joint (col 3 lines 14-18), the longitudinal joint further comprising a first side and a second side (fig 6), the first side including a protrusion having a neck leading to a head (fig 6), the head (7) being larger than the neck (9), and the second side including an opening leading to a cavity (2), the opening being smaller than the head (7) of the first side and at least as large as the neck of the first side (fig 6), and the cavity being within a range of slightly smaller to larger than the head of the first side (fig 6). Curelaru et al discloses a single lumen formed within the elongate tube (fig 6), the longitudinal joint extends throughout an entire length of the sheath (fig 5 – part 13), the longitudinal joint extends from a proximal end of the sheath to a position proximal a distal end of the sheath (fig 5); the longitudinal joint has a depth extending from an external surface of the sheath to a surface of the lumen (col 4 lines 39-41).
3. Regarding claims 29, 31, and 33, Curelaru et al discloses a delivery system comprising a sheath (fig 2) including an elongate tube (1) having at least one lumen (2)

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extending a length of the sheath (fig 2, 5) and a resealable longitudinal joint (fig 5 and col 3 lines 14-18) a guide wire distributed throughout the length of at least one lumen (fig 9), a handle disposed at a proximal portion of the sheath (11 on fig 5), a device coupling the proximal portion of the sheath to a distal portion of the handle (fig 5, fig 9), a device configured to split the longitudinal joint and to allow the sheath to be removed from the guidewire (9); the splitting device further comprising a blade (9) aligned with a longitudinal axis of the ring (15) and being coupled to the surface of the lumen of the ring (fig 9), a height of the blade being sufficient to extend into the lumen of the sheath (9 is larger than lumen) and including a distal edge for cutting the sheath during relative movement between the ring and the sheath (col 4 lines 56-64), the device coupling the proximal portion of the handle is split along the length of the device (fig 5, fig 9, fig 14).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curelaru et al (4,581,019) in view of Campbell et al (5,868,704). Curelaru et al discloses applicant's basic inventive concept of a convertible delivery medical system for medical device, substantially as claimed, with the exception of specifically stating that the lumen is capable of being pressurized up to and over 8 atm, as well as the ring of the delivery system further comprising a guide mandrel. Campbell et al shows both of these features to be old in the medical delivery devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Campbell et al to modify the delivery device of Curelaru et al to make the lumen capable of being pressurized up to and over 8 atm (col 15, lines 18-23) so that it can withstand normal inflation and deflation pressures when the device is in use. It also would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Campbell et al to modify the delivery device of Curelaru et al to add a guide mandrel (col 5 lines 8-12) coupled to the edge of the blade, and configured to be positioned within the lumen of the sheath for the purpose of helping the tube to form.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grayzel (4,921,479) discloses a catheter sheath with longitudinal seam; Schiff (4,473,067) discloses an introducer assembly for intra-aortic balloons and the like incorporating a sliding, blood tight seal; Glowa et al (5,779,697) discloses an


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arthroscopic cannula with fluid seals; Crocker et al (5,295,962) discloses a drug delivery and dilatation catheter; Miyata et al (5,683,347) discloses a balloon catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
NICHOLAS D. LUCCHESI  
SUPERVISOR, ART EXAMINER  
TECHNOLOGY CENTER 3763

Melissa A McCorkle  
Examiner  
Art Unit 3763

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11/14/05